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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,718	12/14/2001	Karl H. Weisgraber	UCAL-222	5282

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EXAMINER
TON, THAIAN N

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/017,718	Applicant(s) WEISGRABER ET AL.	
	Examiner Thai-An N. Ton	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Note that claim 15 is incorrectly dependent upon itself. For the purposes of this Election/Restriction, claim 15 is interpreted to be dependent upon claim 14. Applicant is required to change the dependency of this claim in response to this Office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 14, 15, drawn to gene targeted non-human animals comprising a modified endogenous apolipoprotein E [apoE] allele, and methods of identifying an agent that reduces a phenomenon associated with Alzheimer's disease, classified in class 800, subclasses 3, 13.

II. Claims 1-4 and 19, drawn to gene targeted non-human animals comprising a modified endogenous apolipoprotein E [apoE] allele and a method of identifying an agent that reduces the risk of heart disease, classified in class 800, subclasses 3, 13.

III Claims 5-11, drawn to cells, vector, and nucleic acid comprising a modified non-human apoE gene, classified in class 435, subclass 320.1, 325+, 455, 463.

IV. Claims 12 and 13, drawn to recombinant apoE proteins, classified in class 530, subclass 350+.

V. Claims 16-18, drawn to methods for identifying an agent that reduces apoE4 interaction, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Invention I and II are distinct, as the methods of identifying an agent that reduces a phenomenon associated with Alzheimer's disease requires a materially different and separate protocol, different technical considerations from the methods of identifying an agent that reduces the risk of heart disease. For example, the animal in Invention I would require different technical considerations (for example, its phenotype) for use in the methods of identifying agents that reduce a phenomenon associated with Alzheimer's disease from the animal of Invention II, which would require different technical considerations for use in methods of identifying an agent that reduces the risk of heart disease.

Invention I and Invention III are to distinct products. The animal of Invention I can be used to observe gene function, or as a model for disease or condition. The DNA of Invention II can be used to produce protein *in vitro*.

Invention I and Invention IV are to distinct products capable of separate use. The non-human animal of Invention I is distinct in chemical structure and function from the proteins of Invention IV. Furthermore, the protein of Invention IV is not required for the non-human animal of Invention I, and vice versa.

Inventions I and V are mutually exclusive and independent. The gene targeted non-human animals comprising a modified endogenous apolipoprotein E [apoE] allele of Invention I is not required for the implementation of the methods for identifying an agent that reduces apoE4 interaction of Invention V, and vice versa.

Invention II and III are to distinct products. The animal of Invention I can be used to observe gene function, or as a model for disease or condition. The DNA of Invention II can be used to produce protein *in vitro*.

Invention II and IV are to distinct products capable of separate use. The non-human animal of Invention II is distinct in chemical structure and function from the proteins of Invention IV. Furthermore, the protein of Invention IV is not required for the non-human animal of Invention II, and vice versa.

Invention II and V are mutually exclusive and independent. The gene targeted non-human animals comprising a modified endogenous apolipoprotein E [apoE] allele of Invention II is not required for the implementation of the methods for identifying an agent that reduces apoE4 interaction of Invention V, and vice versa.

Invention III and IV are to distinct products capable of separate use. The nucleic acid sequence of Group III can be used as a probe in hybridization assays. The recombinant apoE proteins of Invention IV can be used to produce antibodies.

Invention III and Inventions V are mutually exclusive and independent. The cells, vector and nucleic acid of Invention III are not required for the implementation of the methods for identifying an agent that reduces apoE4 interaction of Invention V, and vice versa. Furthermore, each of the methods requires a materially different and separate protocol.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the recombinant apoE proteins of Invention IV can be used to produce antibodies.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT
Thái-An N. Ton
Patent Examiner
Group 1632

Deborah Crouch
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